IN THE MATTER OF the Patent Act, R.S.C. 1985, c. P-4, as amended

AND IN THE MATTER of HORIZON PHARMA (the "Respondent") and the medicine Cysteamine Bitartrate sold by the Respondent under the trade name Procysbi

REASONS FOR DECISION
(The Respondent's Motion for Recusal (the "Motion"))

1. On December 3, 2020, the panel (the "**Panel**") of the Patented Medicine Prices Review Board (the "**Board**") seized with this proceeding heard the Motion which sought the following relief:

(a) an Order disqualifying Dr. Mitchell Levine as a Panel member in this proceeding on the ground that there is a reasonable apprehension of bias arising from the statements that he made to the House of Commons Standing Committee on Health (the "**HESA Committee**") on November 23, 2020 and November 27, 2020;

(b) an Order requiring that the Panel be reconstituted, with a proper quorum, to restore at least a second member for the purposes of hearing this case; and

(c) an Order providing directions for the further conduct of the hearing or, alternatively, the re-hearing, of this case.

2. The public must have confidence in the impartial administration of justice in proceedings before the Board and the principles of natural justice require that this Panel be free from any reasonable apprehension of bias when adjudicating an allegation of

excessive pricing under section 83 of the *Patent Act*[1] (the "**Act**"). Accordingly, this Motion raises an important matter which the Panel takes very seriously.

3. The Panel has carefully reviewed and considered the materials filed and the oral submissions of the Parties. For the reasons set out below, the Panel dismisses the Motion. The Panel has concluded that there is no reasonable apprehension of bias arising from the statements that Dr. Levine made to the HESA Committee on November 23, 2020 and November 27, 2020.

A. BACKGROUND

(i) The Proceeding

4. This Motion arises in a proceeding commenced by Board Staff where it is alleged that the Respondent is selling the medicine Cysteamine Bitartrate under the trade name Procysbi ("**Procysbi**") at a price that is excessive under section 83 of the Act.

5. The hearing of this proceeding commenced on November 23, 2020 before a Panel composed of two members of the Board: Ms. Carolyn Kobernick (Chair) and Dr. Mitchell Levine.

6. The question before the Panel is whether the price of Procysbi is excessive under section 83 of the Act. The Panel is required to undertake the sequential analysis prescribed in section 85 of the Act in order to answer this question.

7. First, the Panel must consider the factors enumerated in subsection 85(1) of the Act, which are:

(a) the prices at which Procysbi has been sold in the relevant market;

(b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;

---

[1] R.S.C., 1985, c. P-4.

(c) the prices at which Procysbi and other medicines in the same therapeutic class have been sold in countries other than Canada;

(d) changes in the Consumer Price Index; and

(e) such other factors as may be specified in any regulations made for the purposes of this subsection.

8. The version of the *Patented Medicines Regulations*[2] (the "**Current Regulations**") applicable to this proceeding does not specify any additional factors that this Panel must consider under subsection 85(1)(e) of the Act.

9. If, after considering the subsection 85(1) factors, the Panel is unable to determine whether the price of Procysbi is excessive, then the Panel may consider the additional factors listed in subsection 85(2) of the Act; namely, the cost of making and marketing Procysbi.

10. When assessing the factors set out in section 85 of the Act, the Panel is permitted to consider the Compendium of Policies, Guidelines and Procedures[3] (the "**Current Guidelines**"). However, the Current Guidelines are not binding on the Panel.

(ii) The HESA Committee Meetings

11. On October 26, 2020, the HESA Committee passed a motion to review and study the new PMPRB Guidelines that will take effect on January 1, 2021[4] (the "**New Guidelines**"). The New Guidelines are intended to reflect amendments to the Current

---

2 SOR/94-688.

3 Patented Medicine Prices Review Board, "Compendium of Policies, Guidelines and Procedures" (February 2017), online: <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=492>.

4 Government of Canada, "PMPRB Guidelines" (November 9, 2020), online: <https://www.canada.ca/en/patented-medicine-prices-review/services/legislation/about-guidelines/guidelines.html>.

Regulations set out in *Regulation SOR/2019-298*[5] as amended by *Regulation SOR/2020-126*[6] (collectively, the "**New Regulations**"), which are not yet in force.

12. The Regulatory Impact Analysis Statement ("**RIAS**") that accompanied the New Regulations explains that the New Regulations supplement the factors that the Board must consider when determining whether a price is excessive "to include its value to, and financial impact on, consumers in the health system."[7] As recently confirmed by the Federal Court, the purpose of the amendments reflected in the New Regulations is "to modernize the Board with new regulatory tools and information reporting authority, and to lower patented medicines prices to protect Canadian consumers from the abuse of excessive[ly] pricing."[8]

13. As discussed further below, neither the New Guidelines nor the New Regulations are applicable to this proceeding.

14. In support of the motion to study the New Guidelines, a member of the HESA Committee suggested that the Board be invited to attend one of its meetings to provide a briefing on the New Guidelines. Dr. Levine, in his capacity as Chairperson of the Board (whose mandate includes attending meetings convened by the Minister of Health), and Mr. Doug Clark, in his capacity as Executive Director of the Board, attended the HESA Committee meeting held on November 23, 2020. Dr. Levine made opening remarks, in which he provided background information about the Board and its mandate and the circumstances that gave rise to the development of the New Guidelines. Dr. Levine was followed by Mr. Clark who then explained the changes that are reflected in the New Guidelines (the "**November 23 Meeting**").

---

5 *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR/2019-298.

6 *Regulations Amending the Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR/2020-126.

7 *Regulatory Impact Analysis Statement*, (2019) C. Gaz. II, Vol. 153, No. 17 (*Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR/2019-298), online: <http://www.gazette.gc.ca/rp-pr/p2/2019/2019-08-21/html/sor-dors298-eng.html>.

8 *Innovative Medicines Canada v. Canada (Attorney General)*, 2020 FC 725 at para. 104.

15. On November 27, 2020 Dr. Levine and Mr. Clark returned to respond to HESA Committee members' questions about the New Guidelines (the "**November 27 Meeting**"). The November 27 Meeting, together with the November 23 Meeting, are referred to herein as the "**Meetings**".

16. At the pre-hearing case conference on November 20, 2020, the Parties were advised that the hearing on November 23 would be adjourned to allow Dr. Levine to attend the HESA Committee meeting between 11:00 am and 12:00 pm that day.[9] On November 23, 2020, the hearing was adjourned for this purpose.[10]

17. Several of the statements that Dr. Levine made at the Meetings are at issue on this Motion.

B. POSITIONS OF THE PARTIES

(i) The Respondent

18. The Respondent submits that Dr. Levine's comments at the Meetings, viewed in context, would lead a reasonable and informed person to conclude that he is predisposed and has prejudged certain issues before him in this proceeding, thus giving rise to a reasonable apprehension of bias.

19. Specifically, the Respondent submits that the following statements that Dr. Levine made at the November 23 Meeting are directly relevant to the issues before him in this proceeding, and raise an apprehension that Dr. Levine is unlikely to fairly decide the matter which he is adjudicating, whether consciously or unconsciously:

(a) "In the early 2000s, the pharmaceutical industry began to shift its R and D focus to complex biological drugs that are often used to treat less common conditions and can cost several hundreds of thousands of dollars per year. We have witnessed the upshot of that shift over the past decade, with the average annual cost of the top-selling patented drug increasing by

---

9 Pre-Hearing Case Management Conference Transcript (November 20, 2020), page 30, lines 8-22.

10 Hearing Transcript (November 23, 2020), page 50, lines 10-16.

approximately 1000% and the proportion of high cost drugs, that is drugs costing more than $10,000 per year, rising from 5% to 40% of overall pharmaceutical spending. Yet less than 1% of the population are using these medicines. By any measure, Canadians are paying a great amount of money for this new wave of high cost patented medicine. Of particular concern is that Canada pays the fourth highest prices amongst the 31 OECD countries, 17% above the median price of those countries. Canada is the second-highest in the OECD in terms of how much it spends on patented medicine as a proportion of total health care costs and in per capita spending."[11]

(b) "As expensive drugs for rare diseases account for a rapidly increasing share of total spending, payers are becoming very concerned about sustainability. Not only are these drugs incredibly costly, relative to the top selling products of a few decades ago, their market characteristics shift the balance of power decidedly in the favour of patent holding monopolists when negotiating a reimbursement price with public or private insurers. This point was made rather emphatically by the pan-Canadian Pharmaceutical Alliance, PCPA, in its submission to this committee last year on access to treatments for rare disease. And I quote, 'the PCPA often negotiates under very challenging circumstances starting with an extremely high list price, severe untreated disease, no competing products, and a high patient and healthcare provider expectations to conclude negotiations quickly. As such, the PCPA remains very concerned that the prices achieved through negotiation remain largely unfair, excessive, and not cost effective and the PCPA needs collaborative federal support to manage.'"[12]

---

11 Notice of Motion dated December 1, 2020, at para. 5(a).

12 Notice of Motion dated December 1, 2020, at para. 5(b).

(c) “As members of this committee well know Canada is the only developed country with a public healthcare system that doesn’t include prescription drug price coverage. The PCPA accounts for approximately 43% of total pharmaceutical expenditure in Canada with the remainder being taken up by private insurance and out of pocket payments. If the PCPA believes its power buying is woefully insufficient to secure a fair price from monopolist pharmaceutical companies for the type of drugs that are increasingly dominating the market, one can only imagine how the mixed bag of buyers who account for the remaining 57% of pharmaceutical expenditures in Canada can fare in their efforts to negotiate a price they can afford. As a federal ceiling price regulator the PMPRB exists to protect payers in precisely these circumstances and therefore serves as a proxy for the monopsony power that Canada lacks because of the patchwork nature of pharmaceutical coverage in this country. If one accepts the proposition that an unbridled free market is not in the public interest once it comes to patented medicines, then really the only question is what rules should a regulator apply in seeking to protect consumers from excessive prices in today’s pharmaceutical marketplace.”[13]

(d) “We believe that the final product of our efforts represents an important step towards greater fairness in pricing. Not only bringing Canadian prices more in line with international comparators but also by introducing new pricing tests based on value for money and the health systems affordability. While I recognize that our guidelines have given rise to a great deal of angst on the part of industry, I would ask the committee to consider how that could ever be avoided when the desired outcome of the policy is to lower prices and to reduce total expenditures on pharmaceuticals. To put the matter in another way, what inferences might one draw about these reforms if they did not elicit such a reaction from industry. Nevertheless, a non-excessive price should be a fair price and a

---

[13] Notice of Motion dated December 1, 2020, at para. 8(c).

> fair price means a price that will permit the sustainability of both the healthcare system and the pharmaceutical industry."[14]

20. In addition, the Respondent submits that the following statement made by Dr. Levine at the November 27 Meeting raises a reasonable apprehension of bias:

> "[T]he more life-saving or effective a drug is or dramatic the improvement is, the lower the cost per QALY [quality-adjusted life year] becomes. So, when you're seeing drugs that are at a half a million or one million dollars per quality-adjusted-life-year the implication is that either their price is just way off the chart or in fact it doesn't deliver on the outcome that one would really hope… so, you know, really, really effective drugs, life-saving, life-altering drugs have lower cost per QALY, that's the way that ratio works".[15]

21. Horizon submits that Dr. Levine must be disqualified because his statements at the Meetings reflect preconceived views on two issues before him, which are referred to herein as the "pCPA Issue" and the "QALY Issue".

(a) The pCPA Issue

22. First, Horizon submits that Dr. Levine's comments at the November 23 Meeting would lead a reasonable person to conclude that Dr. Levine has predetermined and prejudged the following issue: whether "prices for rare disease drugs cause the pCPA [pan-Canadian Pharmaceutical Alliance] to be forced under duress to agree to excessive pricing"[16] (the "**pCPA Issue**").

23. In support of this position, Horizon notes that (i) the investigation into the price of Procysbi was triggered by a complaint made by the pCPA to the PMPRB on February 22, 2018, and (ii) in this hearing the Minister of Health of British Columbia submits that the pCPA's negotiated agreement with the Respondent was made under duress and that the terms of its agreement do not reflect a fair value. The Respondent disputes this allegation, and submits that this is a live issue currently before the Panel.

---

14 Notice of Motion dated December 1, 2020, at para. 8(d).

15 Notice of Motion dated December 1, 2020, at para. 9.

16 Written Representations of the Respondent dated December 1, 2020, at para. 32.

24. Accordingly, the Respondent submits that by making the above-noted remarks at the November 23 Meeting, and quoting from a submission made by the pCPA, Dr. Levine publicly sponsored the allegations that the pCPA has made against the Respondent in this proceeding and predetermined the issue of whether high prices for rare disease drugs cause the pCPA to be forced under duress to agree to unfair pricing.

(b) The QALY Issue

25. Second, the Respondent submits that Dr. Levine's remarks regarding QALYs at the November 27 Meeting would lead a reasonable person to conclude that Dr. Levine has predetermined and prejudged the issue of whether Procysbi is excessively priced or does not deliver the expected outcome (the "**QALY Issue**").

26. In support of this submission, the Respondent notes that in this proceeding the CADTH Canadian Drug Expert Committee Recommendation reassessed Procysbi's incremental cost-utility ratio to be over $1 million per QALY. Accordingly, the Respondent submits that by making the statements at the November 27 Meeting that when drugs have a cost-utility ratio of half million or $1 million QALY "the implication is that either their price is just way off the chart or in fact it doesn't deliver on the outcome that one would really hope", Dr. Levine was essentially publicly declaring that either the price of Procysbi is excessive, or it does not deliver the expected outcome. The Respondent submits that both issues are to be determined in this case, yet this statement prejudges both issues before hearing the Respondent's evidence. The Respondent submits that this is fatal to the appearance of fairness.

(ii) Board Staff

27. Board Staff opposes the Motion, and submits that an informed person, reviewing the current situation realistically and practically, and thinking the matter through, would not conclude that Dr. Levine would be unable, consciously or unconsciously, to decide this proceeding fairly. Board Staff submits that the Respondent has not submitted cogent evidence to displace the strong presumption of impartiality on the part of Dr. Levine in his role as a member of an administrative tribunal. Board Staff made several submissions in support of this position, which can be summarized as follows.

28. First, Board Staff submits that Dr. Levine's remarks do not relate to any matter that is before the Panel in this proceeding. In this regard, Board Staff submits that the pCPA Issue is a peripheral issue that will not ultimately assist the Panel in deciding whether the price of Procysbi is excessive under section 83 of the Act. In addition, Board Staff submits that Dr. Levine's remarks related to QALY have no bearing on this proceeding because the QALY of a medicine can only be considered by the Board under the New Guidelines and New Regulations, neither of which apply here.

29. Second, Board Staff submits that Dr. Levine's statements must be understood in the context of his role as Chairperson of the Board. Board Staff submits that Dr. Levine was not offering his personal opinion, or operating in an adjudicative role, but rather he was operating well within his statutory role as Chairperson to inform and report on the Board's mandate. Board Staff submits that in this role, Dr. Levine's remarks reflected statements of publicly available facts, that echoed and reinforced information previously released by the Board. In Board Staff's submission, none of the impugned remarks specifically referenced Procysbi, the medicine cysteamine bitartrate or the Respondent, or reflected any prejudgment of the issues relevant to this proceeding.

C. THE APPLICABLE LAW

30. Impartiality and the absence of bias are critical components of a fair adjudicative process. Decision-makers are required, and expected, to approach every case with impartiality and an open mind,[17] as "public confidence in our legal system is rooted in the fundamental belief that those who adjudicate in law must always do so without bias or prejudice and must be perceived to do so".[18]

---

[17] *Yukon Francophone School Board, Education Area No. 23 v. Yukon Territory (Attorney General)*, 2015 SCC 25 at para. 22.

[18] *Yukon Francophone School Board, Education Area No. 23 v. Yukon Territory (Attorney General)*, 2015 SCC 25 at para. 23, quoting *Wewaykum Indian Band v. Canada*, 2003 SCC 45 at para. 57.

31. The party seeking disqualification bears the burden of proving a reasonable apprehension of bias. The burden is high, as the moving party must displace the presumption of impartiality on the part of the administrative decision-maker or judge.[19]

32. Both Parties agree that the test for reasonable apprehension of bias is well established and was recently affirmed by the Supreme Court of Canada in *Yukon Francophone School Board* as follows: "what would an informed person, viewing the matter realistically and practically — and having thought the matter through — conclude. Would he think that it is more likely than not that [the decision-maker], whether consciously or unconsciously, would not decide fairly".[20]

33. Moreover, in that same decision, the Supreme Court of Canada confirmed that the inquiry into whether a decision-maker's comments or conduct gives rise to a reasonable apprehension of bias "is inherently contextual and fact-specific".[21] The "impugned comments or other conduct must not be looked at in isolation. Rather it must be considered in the context of the circumstances, and in light of the whole proceeding".[22]

D. ANALYSIS

34. This Panel recognizes that all parties who appear before the Board must receive a hearing before panel members who are not only independent and impartial, but also appear to be independent and impartial.

35. After careful review and consideration of the Parties' submissions, the Panel has concluded that the Respondent has not satisfied its burden to prove a reasonable

---

19 *Wewaykum Indian Band v. Canada*, 2003 SCC 45 at para. 59. See also *Yukon Francophone School Board, Education Area No. 23 v. Yukon Territory (Attorney General)*, 2015 SCC 25 at para. 26; *Zündel v. Citron*, 2000 CanLII 17137 at para. 36 (F.C.A.), leave to appeal dismissed 2000 CarswellNat 2877 (S.C.C.), citing *R. v. S. (R.D.*), [1997] 3 SCR 484.

20 *Yukon Francophone School Board, Education Area No. 23 v. Yukon Territory (Attorney General)*, 2015 SCC 25 at para. 20.

21 *Yukon Francophone School Board, Education Area No. 23 v. Yukon Territory (Attorney General)*, 2015 SCC 25 at para. 26.

22 *Yukon Francophone School Board, Education Area No. 23 v. Yukon Territory (Attorney General)*, 2015 SCC 25 at para. 26, quoting *R. v. S. (R.D.*), [1997] 3 SCR 484 at para. 141.

apprehension of bias on a balance of probabilities. As discussed in more detail below, central to the disposition of this motion is the fact that this Panel has the ability to issue an order against the Respondent in this proceeding only if it determines that the price of Procysbi is excessive and, whether or not the price of Procysbi is excessive, depends exclusively on the factors set out in section 85 of the Act. The New Regulations and New Guidelines, which were the subject of the impugned remarks, are irrelevant. When the impugned remarks are considered in their context, the Panel concludes that an informed person, viewing the matter realistically and practically — and having thought the matter through — would not conclude that it is more likely than not that Dr. Levine, whether consciously or unconsciously, would not decide this case fairly. Put more simply, the Panel concludes that the informed person would not conclude that Dr. Levine has or appears to have prejudged any matter at issue in this proceeding as a result of the remarks he made at the Meetings.

(i) The pCPA Issue

36. Dr. Levine's comments at the November 23 Meeting regarding the pCPA do not give rise to a reasonable apprehension of bias for two reasons.

(a) First, the pCPA Issue does not engage a relevant factor under section 85(1) of the Act

37. An informed person, viewing the matter realistically and practically, would not conclude that Dr. Levine's statements regarding the pCPA gives rise to a reasonable apprehension of bias because whether or not prices for rare disease drugs cause the pCPA to be forced under duress to agree to a specific price is irrelevant to the determination of the issue in this proceeding.

38. The ultimate issue for this Panel to decide is whether Procysbi is excessively priced under section 83 of the Act. In making this determination, the Panel is required to consider the subsection 85(1) factors and, only if necessary as described above, the costs of making and marketing the medicine.

39. The fact that (i) the pCPA was the organization that triggered the Board's investigation into Procysbi, and/or (ii) the Minister of Health of British Columbia submits

that the pCPA's negotiated agreement with the Respondent was made under duress, is not relevant to any of the factors under section 85 of the Act.

40. This Panel is not to decide whether the pCPA was forced to negotiate the price of Procysbi under duress. Nor is this Panel to decide more generally whether "prices for rare disease drugs cause the pCPA to be forced under duress to agree to excessive pricing".[23] Rather, the sole issue before this Panel is whether Procysbi is excessively priced under section 83 of the Act based on the factors set out in section 85 of the Act. Dr. Levine's remarks at the November 23 Meeting were not relevant to this issue.

(b) Second, Dr. Levine's remarks do not give rise to a reasonable apprehension of bias when they are considered in their context

41. As explained above, the Supreme Court of Canada has confirmed that the inquiry into whether a decision-maker's comments create a reasonable apprehension of bias requires the impugned comments to be considered in the context of the circumstances, and in light of the whole proceeding.[24] In this case, the Panel is of the view that Dr. Levine's comments, when understood in their context, do not give rise to a reasonable apprehension of bias.

42. Dr. Levine is the Chairperson and chief executive officer of the Board.[25] In this role, Dr. Levine attended the November 23 Meeting to provide an oral briefing to assist the HESA Committee with its review and study of the New Guidelines. Dr. Levine's opening remarks provided the HESA Committee with background information on the Board and the circumstances that led to the Board's development of the New Guidelines, including statistical information about the costs of pharmaceuticals in Canada, the shift towards complex biological drugs used to treat less common conditions and the position of the pCPA regarding the challenges faced by public health authorities when negotiating prices for complex drugs.

---

23 Written Representations of the Respondent dated December 1, 2020, at para. 32.

24 *Yukon Francophone School Board, Education Area No. 23 v. Yukon Territory (Attorney General)*, 2015 SCC 25 at para. 26, quoting *R. v. S. (R.D.)*, [1997] 3 SCR 484 at para. 141.

25 *Patent Act*, R.S.C. 1985, c. P-4, s. 93(2).

43. In making his remarks, Dr. Levine, as Chairperson of the Board, was explaining the matters that the Board considered when developing the New Guidelines.

44. Dr. Levine's quotation from a submission of the pCPA would not be viewed by the informed observer as indicating that he has or appears to have prejudged the evidence related to the pCPA in this proceeding. The submission that Dr. Levine quoted from was a publicly available brief that the pCPA submitted to the HESA Committee on December 7, 2018. By quoting from this public submission, Dr. Levine was explaining to the HESA Committee the perspectives of Canadian payers that the Board considered when developing the New Guidelines. This is not surprising, given that consumer protection is an important mandate of the Board.[26]

45. The remaining impugned comments from the November 23 Meeting reflected statements of publicly available facts, that echoed and reinforced information available in the RIAS which, as explained above, accompanied the New Regulations.

46. Dr. Levine's statements regarding the monopoly position of patentees, and the monopsony power that Canada lacks, echoed the following paragraph of the RIAS:

> "It is often noted that Canada is the only country with a publicly funded health care system that does not include universal pharmaceutical coverage. The result is a patchwork of public and private payers who lack the national buying power to counter the **monopoly position of patentees**. That monopoly position is bolstered by an increasing proportion of public and private spending that is taken up by high-cost medicines with few or no therapeutic alternatives. Requiring the PMPRB to consider the pharmacoeconomic value of these medicines will ensure that the concept of opportunity cost is taken into account in determining whether their price is excessive."[27] [Emphasis added]

---

26 *Celgene Corp. v. Canada (Attorney General)*, 2011 SCC 1 at paras. 27 and 28.

27 *Regulatory Impact Analysis Statement*, (2019) C. Gaz. II, Vol. 153, No. 17 (*Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR/2019-298), online: <http://www.gazette.gc.ca/rp-pr/p2/2019/2019-08-21/html/sor-dors298-eng.html>.

47. Similarly, Dr. Levine's comments regarding the shift in R&D focus to high cost, complex drugs used to treat rare diseases echoed the following paragraphs of the RIAS:

> "… R&D is increasingly focused on high-cost medicines, such as biologics, genetic therapies targeted to smaller patient populations and medicines for rare diseases. The risk of excessive pricing is often greater for these products since they have few, if any, competitive substitutes and demand for new and better treatments among the more severely affected population is very high. This is especially true for medicines that are the first of their kind, or for which alternatives are less effective or have less tolerable side effects.
>
> The current market dynamic has led to affordability challenges for consumers that, if left unaddressed, pose a very real threat to the sustainability of the pharmaceutical system in Canada. Between 2007 and 2017, the average annual cost of treatment for the top 10 selling patented medicines in Canada increased by 800% and the number of medicines in Canada with annual per-patient treatment costs of at least $10,000 swelled from 20 to 135. These high-cost medicines now account for 40% of new patented medicines coming under the PMPRB's jurisdiction every year. Fully 30% of public and private insurer spending is allocated to these medicines, which cover less than 2% of beneficiaries."[28] [Emphasis added]

48. Further, Dr. Levine did not make any comments at the November 23 Meeting concerning Procysbi, cysteamine bitartrate or the Respondent.

(ii) The QALY Issue

49. Dr. Levine's remarks at the November 27 Meeting regarding QALYs do not give rise to a reasonable apprehension of bias for the following two reasons.

(a) First, the QALY of Procysbi is not a relevant factor under section 85 of the Act

50. An informed person, viewing the matter realistically and practically, would not conclude that Dr. Levine's statement regarding QALYs gives rise to a reasonable

---

[28] *Regulatory Impact Analysis Statement*, (2019) C. Gaz. II, Vol. 153, No. 17 (*Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR/2019-298), online: <http://www.gazette.gc.ca/rp-pr/p2/2019/2019-08-21/html/sor-dors298-eng.html>.

apprehension of bias because QALYs are irrelevant to the determination of the issue in this proceeding.

51. As described above, Parliament prescribes in section 85 of the Act the sequential analysis that this Panel must undertake when determining whether Procysbi is excessively priced under section 83 of the Act. The first step is to consider the subsection 85(1) factors. If, after considering the subsection 85(1) factors, the Panel is unable to determine whether the price of Procysbi is excessive, then the Panel may consider the additional factors listed in subsection 85(2) of the Act; namely, the cost of making and marketing the medicine.

52. Section 4.4 of the New Regulations introduces new factors that must be considered by the Board pursuant to subsection 85(1)(e) of the Act:

> "4.4 For the purposes of paragraph 85(1)(e) of the Act, the other factors that the Board shall take into consideration to determine whether a medicine that is sold in any market in Canada after December 31, 2020 is being or has been sold at an excessive price are the following:
>
> (a) the medicine's pharmacoeconomic value in Canada;
>
> (b) the size of the market for the medicine in Canada; and
>
> (c) the gross domestic product in Canada and the gross domestic product per capita in Canada." [Emphasis added]

53. When the New Regulations and New Guidelines come into force on January 1, 2021, the Board will be permitted to consider QALYs in its assessment of a medicine's pharmacoeconomic value under subsection 4.4(a) of the New Regulations when determining whether a medicine is excessively priced under section 83 of the Act.

54. However, the New Regulations are not in force and, in deciding the present case, this Panel is only permitted to consider the factors prescribed in section 85 of the Act. Even if the New Regulations were in force, pursuant to section 2.1 of the New Regulations, this Panel would not be permitted to consider the new factors prescribed

by the New Regulations in deciding this case.[29] Accordingly, Procysbi's pharmacoeconomic value in Canada (including the QALY of Procysbi) is not relevant to the Panel's determination of whether Procysbi is excessively priced under section 83 of the Act.

(b) Second, Dr. Levine's remarks do not give rise to a reasonable apprehension of bias when they are considered in their context

55. At the November 27 Meeting, Dr. Levine was speaking generally about QALYs in the context of the amendments reflected in the New Regulations, which will require the Board to include pharmacoeconomics in its analysis of whether a price is excessive. These amendments will, in turn, be operationalized in the New Guidelines.

56. Dr. Levine's comment must be considered in the context of the entire conversation between the HESA Committee members, Dr. Levine and Mr. Clark. Dr. Levine made the impugned comment in response to a question posed by a member of the HESA Committee who had voiced concerns about the democratic legitimacy of putting a price on human life via QALYs through regulation:

> "Now, if some of the drugs we're talking about here are obviously life-saving drugs and we're setting a limit on how much we're willing to pay in terms of a cut-off in cost per QALY, aren't we basically putting a price on life as to what price our government considers acceptable? How much are we willing to pay to save a life?
>
> I would ask.... Maybe this is an unfair question, but from a democratic perspective, to put a value on life by regulation seems to me somewhat undemocratic, if it is done by regulation rather than by going through Parliament. Maybe that's an unfair question. I think it's a bit of a philosophical question."[30]

57. In answering that question, Dr. Levine explained what QALYs are and the role that they play under the New Guidelines. In considering Dr. Levine's answer, it is helpful

---

29 Section 2.1 of the New Regulations states as follows: "Sections 4.1 to 4.4 do not apply to any medicine for which a drug identification number has been assigned under the Food and Drug Regulations before August 21, 2019." Procysbi was assigned a drug identification number well before this deadline.

30 House of Commons, Standing Committee on Health, *Evidence*, No. 009 (27 November 2020) at 12.

to review the QALY thresholds discussed in the RIAS that accompanied the New Regulations:

> "The 40% average reduction in price for high-priority medicines assumes that the PMPRB would apply a $50,000 cost-per-QALY threshold for medicines for standard diseases (including cancer), a $150,000 threshold for medicines for rare diseases, and a $35,000 threshold for medicines with a high-prevalence population."[31] [Emphasis added]

58. When Dr. Levine referred to drugs with a cost-utility ratio of $500,000 or $1 million QALY as being "off the chart" or failing to deliver on the expected outcome, he was stating a fact: when compared to the QALY thresholds anticipated in the RIAS, a cost-utility ratio of $500,000 or $1 million QALY is extraordinary under the New Regulations and New Guidelines.

59. A reasonable and informed person would understand that Dr. Levine was trying to answer the question asked by the member of the HESA Committee, and that Dr. Levine (i) did not discuss the QALY of Procysbi, (ii) did not discuss whether he accepted CADTH's assessment of the QALY of Procysbi, and (iii) did not signify whether QALYs are appropriate mechanisms for evaluating expensive drugs for rare diseases.

60. For all of these reasons, an informed person, viewing the matter realistically and practically — and having thought the matter through — would not conclude that, as a result of the statements made by Dr. Levine at the Meetings, it is more likely than not that Dr. Levine has or appears to have prejudged or predetermined the issue of whether Procysbi is excessively priced under section 83 of the Act, and would not conclude that Dr. Levine, whether consciously or unconsciously, would not decide this matter fairly.

---

[31] *Regulatory Impact Analysis Statement*, (2019) C. Gaz. II, Vol. 153, No. 17 (*Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR/2019-298), online: <http://www.gazette.gc.ca/rp-pr/p2/2019/2019-08-21/html/sor-dors298-eng.html>.

E. DISPOSITION

61. For the foregoing reasons, the Panel denies the Motion. The hearing of this proceeding will re-commence, with the Panel as presently constituted, on January 11, 2021 in accordance with the Scheduling Order dated September 8, 2020.[32]

Dated at Ottawa, this 24th day of December, 2020.

E-SIGNED by Carolyn Kobernick
on 2020-12-24 10:40:55 EST

Signed on behalf of the Panel by
Carolyn Kobernick

Panel Members

Carolyn Kobernick
Mitchell Levine

Counsel for Board Staff

David Migicovsky
Christopher Morris
Courtney March
Timothy Jolly

Counsel for the Respondent

Sheila Block
Andrew Shaughnessy
Stacey Reisman

Counsel for the Province of British Columbia

Sharna Kraitberg

Counsel for the Panel

Sandra Forbes
Megan Percy

---

[32] In the Matter of Horizon Pharma and the Medicine Cysteamine Bitartrate (8 September 2020), online: <https://www.canada.ca/en/patented-medicine-prices-review/services/hearings/status-ongoing-proceedings/order-regarding-scheduling-procysbi.html>.